



DEPARTMENT OF HEALTH & HUMAN SERVICES

465
Public Health Service
Mid-Atlantic Region

Telephone (201) 331-2904

September 29, 1997

Food and Drug Administration
Waterview Corporate Center
10 Waterview Blvd., 3rd Floor
Parsippany, NJ 07054

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

John Walters, President
Bloodline, Inc.
3 Garret Mountain Plaza, Suite 302
West Paterson, New Jersey 07424

RELEASE

REVIEWED BY AZ
C.O.

10/1/97
DATE

FILE NO.: 97-NWJ-51

Dear Mr. Walters:

During an inspection of your blood bank located at 3 Garret Mountain Plaza, West Paterson, New Jersey, on 8/4 through 8/14/97, our investigators documented serious violations of Section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act and the current good manufacturing practices for blood and blood components as prescribed in Title 21, Code of Federal Regulations (21 CFR), Subchapter F, Parts 600-680, as follows:

1. Autologous units that did not meet the homologous donor criteria were shipped interstate as recovered plasma for use in further manufacturing (non-injectable).
Examples:
 - a. Donor (unit 01E03771) collected on 7/2/97 admitted to ear piercing in 10/96.
 - b. Donor (unit 24E0041) admitted to a history of kidney cancer and had prostate cancer at the time of the draw on 6/2/97.
 - c. Donor (unit 07E01485), a hospital worker, admitted to being exposed to hepatitis on 6/23/97.
 - d. Donor (unit 25E00908) admitted to a history of hepatitis during donations on 6/6/97 and 6/20/97.
2. Failure to submit an error and accident report regarding a shipment of recovered plasma (unit 25E00908) from an autologous donor who admitted to a history of "non A and non B viral hepatitis". The receiving facility (a plasma broker who sells plasma for use in the manufacturing of unlicensed, non-injectable products) was not notified that the donor has a history of hepatitis.

3. Lack of Quality Control review to ensure that written procedures (SOP's) are accurate and reflective of current practices. For example:
 - a. Written procedure entitled, Donor Suitability and Collection--Medical Interview and Observations (██████), dated 9/93, is incomplete in that it does not address all deferral policies such as questions concerning HIV-1 Group O: "Have you lived or traveled to any African country since 1977?"

In addition, the procedure does not describe the deferral policy for pregnancy.
4. The blood bank failed to follow written procedure entitled, Donor Suitability and Collection--Physician Request/Approval (██████), dated 11/91, in that approval from the designated donor's physician is required for multiple donations within 8 weeks. Examples:
 - a. A designated donor donated initially on 6/5/97 (unit 07E01478) and made a subsequent donation (unit 07E1482) within 12 days on 6/17/97.
 - b. A designated donor donated initially on 7/2/97 (unit 25E01167) and a subsequent donation (unit 25E01175) was drawn within 20 days on 7/21/97.

The above identification of violations is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to assure adherence with each requirement of the Good Manufacturing Practices Regulations is being followed. Federal agencies are advised of the issuance of all warning letters about drugs and devices so that they may take this information into account when considering the award of contracts.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action without further notice. This includes seizure and/or injunction.

You should notify this office in writing within 15 working days of receipt of this letter, of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to prevent the recurrence of similar violations. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

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Your reply should be sent to the Food and Drug Administration,
New Jersey District Office, 10 Waterview Blvd, 3rd Floor,
Parsippany, New Jersey 07054, Attention: Andrew Ciaccia,
Compliance Officer.

Very truly yours,



DOUGLAS ELLSWORTH
District Director
New Jersey District Office

AC:slw